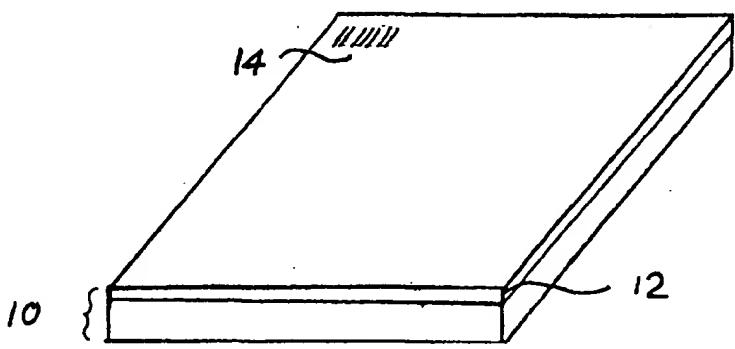


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(21) International Application Number: PCT/US99/16042 (22) International Filing Date: 14 July 1999 (14.07.99) (30) Priority Data: 09/119,021 20 July 1998 (20.07.98) US (71) Applicant (for all designated States except US): NOVEN PHARMACEUTICALS, INC. [US/US]; 11960 S.W. 144th Street, Miami, FL 33186 (US). (71)(72) Applicant and Inventor: JONES, William, Neil [US/US]; 8261 S.W. 162nd Street, Miami, FL 33157 (US). (74) Agent: KOLMAN, Jay, G.; Noven Pharmaceuticals, Inc., 11960 S.W. 144th Street, Miami, FL 33186 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: A METHOD OF INDIVIDUALLY TRACKING AND IDENTIFYING A DRUG DELIVERY DEVICE  (57) Abstract A method of and system for identifying an individual drug delivery device and tracing its ownership. An individual drug delivery device, such as a patch, is coded with a unique identifier. Such coding is performed by using a bar code or by storing the identifier in a memory device in the drug delivery device. A database contains a record of the identifier, representing the drug delivery device. The identifier is read upon a transfer of the drug delivery device and the database is updated to include information such as the date of the transfer, the identity of the transferee and the prescribing physician. The ability to retrieve such information regarding specific drug delivery devices can result in the prevention of abuse of controlled substances contained therein.		

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A METHOD OF INDIVIDUALLY TRACKING AND IDENTIFYING
A DRUG DELIVERY DEVICE

5

Background of the Invention

10 The invention relates generally to drug delivery devices. Specifically, the present invention relates to the tracking and identification of an individual prescription drug delivery device, such as an adhesive patch, and involves encoding the drug delivery device with pertinent information.

15

While there is no limitation on the type of drug that can be used with the present invention, the invention has particular applicability for "controlled substances" such as those listed in the regulations promulgated pursuant to the Food, Drug and cosmetic Act, 20 21 C.F.R. §§ 1308 et seq., and include substances having a stimulant or depressant effect on the central nervous system. Because stimulant drugs have a high potential for abuse, the U.S. Drug Enforcement Administration 25 (DEA) has placed stringent controls on their manufacture, distribution and prescription. For example, the DEA requires special licenses for these activities.

30 One such prescription stimulant drug is methylphenidate (MPH). MPH, manufactured and sold by Novartis Pharmaceuticals Corporation (formerly Ciba-Geigy) under the brand name Ritalin®, is used in the treatment of attention deficit and/or hyperactivity 35 disorders in both children and adults. Experts estimate that such disorders affect 3.5 million children and 17

million adults -- and perhaps even as much as 10 percent of the American population. MPH helps individuals suffering from such disorders stay calm and focused, and often improves their behavior, grades and even their self esteem. About 1.5 million school-age youngsters have been prescribed MPH in mid-1995, with more recent estimates climbing to about 2.4 million.

However, use for illicit, non-medicinal purposes is being increasingly reported particularly among college and high school students. In 1994, a national high school survey (Monitoring the Future) indicated that non-prescription use of MPH doubled among high school seniors between 1993 and 1994, resulting in more seniors abusing MPH than are actually prescribed it legitimately. Similar to cocaine or amphetamines in the nature and duration of their effects, abusers are crushing Ritalin[®] tablets into powder which they then snort to get a quick high.

20

Diversion or abuse of MPH is not however limited to students. Diverse segments of the population from health care professions to street addicts have also been implicated. Organized drug trafficking groups are using various schemes to obtain MPH for resale on the illicit market. According to the DEA, MPH ranks among the most frequently reported controlled pharmaceuticals stolen from licensed handlers.

Law enforcement and other authorities confiscate prescription drugs and specifically, controlled substances, from unauthorized users or unlicensed handlers. It would be useful, to be able to identify the specific product, such as the individual drug delivery device, and be able to trace the origin of that specific product to determine the identity of the last licensed handler of the product, the prescribing

physician, pharmacy or patient, etc. Currently, there is no way to identify the ownership or trace the origin of a prescription drug once it is removed from the prescription packaging.

5

Presumably, if a legitimate handler believes that the individual prescription drugs it dispenses can be traced back to him or her, the handler will be less inclined to distribute the drug illegally and will take greater precautions against loss or theft. The criminal penalties for illegal distribution and use of controlled substances are severe. Thus, providing authorities with a system for accurately identifying the last known legitimate handler of or other pertinent information regarding a particular prescription drug product would help to reduce the potential for abuse and illegal distribution of the product. It would also make available more of the supply of the drug for use by legitimate users with a medical need.

10
15
20

Placing the drug in a delivery system that can control the release rate of the drug in the body or to a site of application, such as an adhesive patch, can help to reduce the potential for abuse of the drug over other conventional dosage administration forms. Nevertheless, the potential for abuse and misuse still exists even with the use of such patches.

25
30

Summary of the Invention

Having recognized the above described problem and need, the inventors have developed the following solution, which is embodied in the present invention. The invention is a system for identifying an individual drug delivery device and tracing its ownership. It will be apparent to one skilled in the art that the invention

35

has applicability with a variety of drug delivery devices, forms and drugs.

In one embodiment of the invention, an individual drug delivery device is encoded with a unique identifier, usually during or soon after its manufacture. In addition to reducing the potential for abuse of the drug through insufflation or injection, the use of a drug delivery device such as an adhesive patch facilitates such coding of individual products. The identifier may be a visible marking such as an alphanumeric string or a bar code and is indelibly printed onto the drug delivery device. In the case of a patch, the visible identifier may be printed onto the backing of the patch. Such an identifier may be recognizable by a human or by an electronic and/or optical device, such as a scanner.

Once the unique identifier has been placed on or in the drug delivery device, a corresponding identifier is created in a database. Information corresponding to each drug delivery device is added to the database as the devices are distributed. At each level of distribution, the individual device identifiers can be scanned, causing relevant information, such as the name of the handler and the date, to be transmitted and appended to the database at a location corresponding to the device identifier. Usually, more than one drug delivery device is transferred between handlers; accordingly, the packaging of the devices, such as a box, will contain a separate identifier corresponding to the devices contained therein. In those cases, the box identifier is scanned causing the data corresponding to multiple device identifiers in the database to be updated with the same handler information. Ultimately, when a drug prescription is filled by the last handler, the individual devices given to the user are scanned

causing the database to be updated with information regarding the end-user to whom the individual device was dispensed. Database updates can be performed immediately upon scanning or at some later time.

5

Under the present invention, authorities have the ability to accurately identify and trace the ownership of any of the drug delivery devices found or confiscated from an unauthorized user. Using the unique identifier
10 on or in an individual drug delivery device, authorities can access the database and obtain information regarding the device such as the identities of: the person to whom the drug was dispensed, the pharmacy or other handler that dispensed the drug and any preceding handlers, such
15 as distributors, of the device. Also, the obtained information can include the date when the device came into the possession of each of the handling parties listed.

20

Using this information, authorities are better able to investigate and reduce the occurrence of illegal distribution or theft of the drug delivery devices, which, as discussed, can contain controlled substances such as MPH. In addition, knowledge that such
25 information is available to authorities will serve to diminish any inclination a handler may have to distribute the drug illegally. It will also encourage all handlers to take greater precautions against loss or theft or the drug delivery devices. Furthermore, the
30 reduction of abuse and illegal distribution of the controlled substance contained in the drug delivery device will make available more of the supply of the drug for use by legitimate users with a medical need.

35

In an alternative embodiment of the present invention, the drug delivery device comprises a memory device such as a microchip or Radio Frequency

Identification (RFID) tag instead of visible markings. In a patch, the microchip or RFID tag can be disposed on or in the backing layer of the patch. The memory device serves to uniquely identify the drug delivery device.

5 All pertinent information regarding the delivery device, such as the identities of the handlers and the legitimate user as well as the prescribing physician, can be stored in the microchip or RFID tag itself. Upon recovery of such a drug delivery device, authorities
10 can, with the assistance of a microchip or RFID reader, extract the information from the microchip or RFID tag contained in the delivery device. A database may be used to provide additional information regarding the specific drug delivery devices, or in the situation
15 where the memory device is a read only memory device. The availability of this information with or without the use of a database has the same beneficial effect in reducing abuse, illegal distribution and theft as does the above described embodiment of the present invention.

20

Other features and advantages of the present invention will become apparent to those skilled in the art from the following detailed description. It should be understood, however, that the detailed description
25 and specific examples, while indicating preferred embodiments of the present invention, are given by way of illustration and not limitation. Many changes and modifications within the scope of the present invention may be made without departing from the spirit thereof,
30 and the invention includes all such modifications.

Brief Description of the Drawings

The present invention will be described below with
35 reference to the accompanying drawings, wherein:

Figure 1 illustrates a uniquely identifiable drug

delivery device according to the present invention, shown as a patch, upon which a bar code identifier is placed;

5 Figure 2 illustrates a uniquely identifiable drug delivery device according to the present invention, shown as a patch, upon which an alphanumeric string identifier is placed;

 Figure 3 illustrates the information stored in a database for a particular drug delivery device; and

10 Figure 4 illustrates a uniquely identifiable drug delivery device according to the present invention, shown as a patch, within which a memory device is disposed.

15

Detailed Description of the Preferred Embodiments

20 As described herein with reference to the accompanying drawings, the present invention provides a method and system for identifying and tracing the ownership of an individual drug delivery device. This allows authorities to investigate more effectively any illegal distribution or theft of drug delivery devices, specifically those devices containing controlled substances. It also has the effect of reducing abuse and making available more of the supply of the controlled substance for use by legitimate users.

30 While the descriptions herein primarily refer to the identification of a patch for delivering a controlled substance such as MPH, it will be apparent to one skilled in the art that the invention has applicability to other drug delivery devices and drugs.

35 Accordingly, as used herein, the term "drug delivery device" shall further include aerosol canisters such as those used for inhalation therapy, pre-filled syringes,

IV bags, bottles, ampules, tamper-proof packaging and any unit-dose drug packaging.

The term "drug" as used herein is intended to have the broadest meaning and includes at least one of any therapeutic, prophylactic, pharmacological or physiological active substance, or mixture thereof, which is delivered to a mammal to produce a desired, usually beneficial, effect. More specifically, any agent which is capable of producing a pharmacological response, localized or systemic, irrespective of whether therapeutic, diagnostic or prophylactic in nature, is within the contemplation for use with the invention. It should be noted that the agents or drugs may be used singularly or as a mixture of two or more agents or drugs, and in amounts sufficient to prevent, cure, diagnose, mitigate or treat a disease or condition, as the case may be. The invention has particular applicability for substances which have or can create an addictive, habit-forming or dependency effect or withdrawal symptoms upon cessation of usage. It is also applicable for use with substances which are or may be lethal, toxic or may cause serious adverse physiological effects if taken or administered in too great a dose or quantity, such as anabolic steroids and hormonal substances such as testosterone and substances having a stimulant or depressant effect on the central nervous system.

In a first embodiment of the present invention, an individual drug delivery device is encoded with a unique identifier, usually soon after its manufacture or as one of the final steps in its manufacture. The identifier allows a particular device to be differentiated from all others. Typical drug delivery devices facilitating such coding are patches. As used herein the term "patch" refers to any drug containing device, system,

composition, bandage, plaster, and the like, that is affixed to the skin or mucosa of a subject for systemic or local administration of the drug. Such devices for transdermal application are, for example, described in references such as U.S. Pat. Nos. 4,994,267 and 5,474,783, both assigned to Noven Pharmaceuticals, Inc., which are incorporated herein by reference. Exemplary devices for transmucosal application are described in U.S. Pat. No. 5,446,070 assigned to Noven Pharmaceuticals, Inc., which is incorporated herein by reference. Such devices typically have a "backing" which facilitates encoding by printing or labeling. Suitable materials that can be used, singularly, in combination, as laminates or as coextrusions, to form the backing are well known in the art and include films or sheets of polyethylene, polyester, polypropylene, polyurethane, polyolefin, polyvinyl alcohol, polyvinyl chloride, polyvinylidene, polyamide, vinyl acetate resins, BAREX[®], ethylene/vinyl acetate copolymers, ethylene/ethylacrylate copolymers, metal-vapor deposited films or sheets thereof, rubber sheets or films, expanded synthetic resin sheets or foils and papers.

Various types of coding can be used under the present invention. Two examples are bar codes and alphanumeric strings. Referring now to the drawings, it should be noted that the figures are illustrative in nature and are not drawn to scale. Figure 1 shows a patch 10 as the drug delivery device on which is placed a bar code 14 to uniquely identify the device. The bar code 14 can be printed on any area of the backing 12 of the patch 10. Figure 2 shows a patch 20 as the drug delivery device, similar to that of Figure 1, but where an alphanumeric string 24 is placed on backing 22 to uniquely identify the device. The alphanumeric string 24 can be a serial number or other string of characters of any length. By its nature, the alphanumeric string

is more easily discernable by a person than is the bar code. Both types of codes, however, are readable by known electronic scanning devices. It is intended that other variations on the type of coding fall within the scope of this invention.

Preferably, the printing of a code is performed with waterproof, indelible ink such that the code cannot be removed without destroying the patch itself. Alternatively, the coding can be incorporated into the drug-delivery device during production. For example, bar coding and alphanumeric strings can be printed on the underside of the backing layer 12 and 22 so that the coding cannot not be altered or removed by solvent. The patch would effectively have to be destroyed to tamper with the coding. Yet, the coding could be read through the backing layer 12 and 22.

According to the present invention, once a drug delivery device, such as a patch, has been encoded with an identifier, a corresponding identifier is placed into a database. While this can be accomplished at any time, placing an entry into a database corresponding to the actual device is preferably done by the manufacturer promptly upon manufacture of the device. The database itself preferably resides with the manufacturer but can be located anywhere. In addition to the identifier, the entry made into the database can include such information as the name and quantity of the drug contained in the device, the date of manufacture, and the place of manufacture.

The device is then packaged for sale and distribution. Individually packaged patches can include an additional identifier on the packaging material itself. Furthermore, as multiple drug delivery devices are often packaged and distributed in sets, boxes

containing such sets can be coded with an identifier representing and identifying the individually coded devices contained therein.

5 The present invention is not limited by the number of channels of distribution that may be in place with respect to any specific type of drug delivery device. Handlers of controlled substances must be licensed by the appropriate authorities, whether the handler is a
10 bulk distributor of pharmaceutical products or a local pharmacist. When a particular device is transferred from one party to another, such as in a sale between two handlers, the identifier of the transferred device is recorded and the database is updated with information
15 pertaining to the transfer. This recording of the device identifier, in the case of bar coding, can be done by an electronic scanning device. In the case of alphanumeric strings, the recording can be done electronically or by a person. The database is then
20 updated with information such as the name of or code representing the identity of the transferee of the device, and the date of the transfer. In the case of multiple devices transferred in a prepackaged box, the identifier on the box is recorded. Upon transfer of the
25 box identifier to the database, information pertaining to all of the individual devices contained in the box are updated accordingly. Similar updates to the database are made whenever possession or ownership of an individual device is transferred. The recording of
30 information and the updating of the database should be accomplished at the time of transfer of possession.

 Ultimately, when a drug prescription is filled by the last licensed handler for an end-user of the device,
35 the information added to the database is, at minimum, the identity of the end-user to whom the device was transferred. Additional information added to the

database can include the address of the patient, the RX#, the MD#, the identity of the prescribing physician, the DEA#, the pharmacy # and the date of dispensation or transfer.

5

Figure 3 illustrates a sample set of the information stored in the database for a particular drug delivery device. The data set 30 all corresponds to the individual drug delivery device coded with the identifier 31 "980704123456". This identifier represents the bar code symbol or is the alphanumeric string coded onto the actual device. The data set 30, as shown in Figure 3, also contains the name and quantity of the drug contained in the device 32, "methylphenidate - 20mg". The manufacturer information 33, "ABC Manufacturing Co." is also included. The above describe data is usually entered into the database before the device is initially transferred from manufacturer. Next, the first date of transfer 34 "980720" is shown as is the transferee 35 "XYZ Distribution Inc." A subsequent transfer to a pharmacy is shown by the second date of transfer 36 "980727" and the transferee 37 "Joe Pharmacist". Finally, the last recorded transfer is shown by the third date of transfer 38 "980803" and the transferee "Jane D. Patient" who presumably is the end-user.

Police and other authorities often find or confiscate drug delivery devices containing controlled substances from unauthorized users and illegal distributors. So long as the database has been updated, under the present invention, authorities have the ability to accurately identify and trace the ownership of a particular drug delivery device. Using the unique identifier on the individual drug delivery device, authorities can access the database and obtain information regarding the device, such as the identities

of: the person to whom the drug was dispensed, the pharmacy or other handler that dispensed the drug and any preceding handlers, such as distributors, of the device. Also, as discussed, the obtained information
5 can include the date when the device came into the possession of each of the handling parties listed.

Using this information, authorities are better able to investigate and reduce the occurrence of illegal
10 distribution or theft of the drug delivery devices, which, as discussed, can contain controlled substances such as MPH. For example, if the authorities were to confiscate from an unauthorized user the drug delivery device identified in Figure 3, based on the code found
15 on the device and by accessing the database, they would know immediately that the device was known to be in the possession of Jane D. Patient on August 3, 1998. Such information would greatly assist in their investigation of the unauthorized sale or use of the controlled
20 substance.

Furthermore, knowledge that such information is available to authorities will serve to diminish any inclination a handler may have to distribute the drug
25 illegally. It will also encourage all handlers to take greater precautions against loss or theft or the drug delivery devices. An additional benefit of the present invention is that the reduction of abuse and illegal distribution of the controlled substance contained in
30 the drug delivery device will make available more of the supply of the drug for use by legitimate users with a medical need.

In an alternate embodiment of the present
35 invention, the above described method of tracking is implemented with drug-delivery devices that include a programmable microchip or a radio frequency

identification (RFID) tag. In the case of a patch, a microchip or an RFID tag can be incorporated into the backing layer during production of the patch. Figure 4 illustrates a drug delivery device under the present invention, such as a patch 40, wherein a memory device 44, such as a microchip or RFID tag, is disposed within the backing layer 42. Alternatively, the programmable microchip or RFID tag is affixed onto the backing layer of the patch during later stages of the production process, before the device is pouched. Thin and flexible RFID tags are known in the art. Moskowitz et al., in U.S. Pat. No. 5,528,222, disclosed such an RFID tag having a semiconductor circuit with logic, memory, and a radio frequency circuit in a thin and flexible package for use with such items as credit cards, passports, admission tickets and postage stamps.

Under the present invention, there are certain advantages to using microchips or RFID tags in drug-delivery device over barcodes. For example, while a bar code indicates an identification number for a specific drug delivery device, a microchip or RFID tag allows for additional information to be stored with the drug-delivery device, such as a physician #, a vendor #, etc. Unlike barcodes, information can be read, with a microchip or RFID reader, from the microchip or RFID tag on the patch while the patch is applied to the skin of the user and without removal of clothing. Also, RFID and microchip readers tend to be less expensive than bar code scanners.

It is envisioned that various types of RFID tags will be used in accordance with the present invention. The use of passive RFID tags, those which rely on power from an external reader, is preferred. It is also possible, however, to use active RFID tags, those which contain their own power supplies, providing they are

sufficiently thin to be disposed on or in the drug delivery device. The various RFID tags contain differing memory capacities and operate in different frequency ranges. It will be apparent to one skilled in the art that the present invention is not limited by such factors.

It is intended that the invention, as described herein, include all variations and modifications as fall within the scope of the claims and equivalents thereof.

What Is Claimed Is:

1. A method of identifying and tracing the ownership of an individual drug delivery device, the
5 method comprising:

coding said individual drug delivery device with a code uniquely identifying the individual drug delivery device;

placing said code in a database; and

10 adding information to said database corresponding to said code upon a transfer of possession of said device, wherein said information comprises at least one of the identity of a transferee in said transfer, the identity of a prescribing physician, the
15 identity of a dispensing pharmacy, the date of said transfer, and the name and amount of a drug contained in said device.

2. A method according to claim 1, wherein the
20 coding of said device is in a form selected from the group consisting of a bar code, an alphanumeric string, a microchip and an RFID tag.

3. A method according to claim 2, further
25 comprising:
storing additional information in said one of a microchip and RFID tag, said additional information consisting essentially of at least one of the identity of a prescribing physician, the identity of a dispensing
30 pharmacy and the date of said transfer.

4. A method according to claim 1, wherein said
code is readable by means of electronic and visual means.

35

5. A method according to claim 1, wherein said drug delivery device is selected from the group

consisting of aerosol canisters, pre-filled syringes, IV bags, bottles, ampules, tamper-proof packages, unit-dose packages, patches, and iontophoretic devices.

5 6. A method according to claim 1, wherein said drug delivery device is a patch which comprises a backing, and said code is printed code on a surface of said backing.

10 7. A method according to claim 1, wherein said drug is a controlled substance.

8. A system for uniquely identifying and tracing ownership of a drug delivery device, said system
15 comprising:

an individually coded drug delivery device including

a carrier for containing a quantity of a drug;
a code disposed on said carrier for uniquely
20 identifying said individual device; and

a database for storing said code and information pertaining to said device upon a transfer of possession of said device, wherein said information comprises at least one of the identity of a transferee
25 in said transfer, the identity of a prescribing physician, the identity of a dispensing pharmacy, the date of said transfer, and the name and amount of a drug contained in said device.

30 9. A system according to claim 8, wherein said code is in a form selected from the group consisting of a bar code, an alphanumeric string, a microchip and an RFID tag.

35 10. A system according to claim 8, wherein said code is readable by means of electronic and visual means.

11. A system according to claim 8, wherein said carrier is a patch which comprises a backing, and said code is printed code on a surface of said backing.

5

12. A system according to claim 8, wherein said drug is a controlled substance.

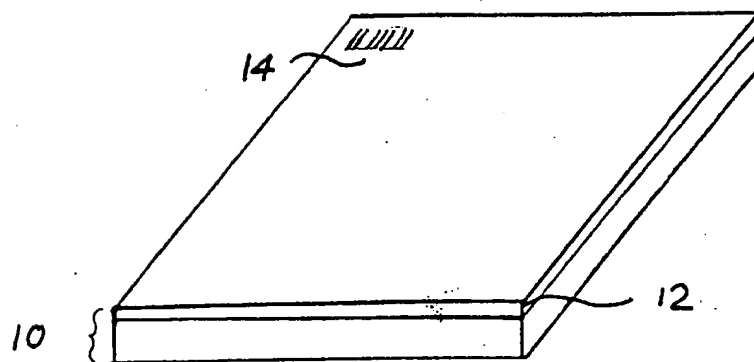


FIGURE 1

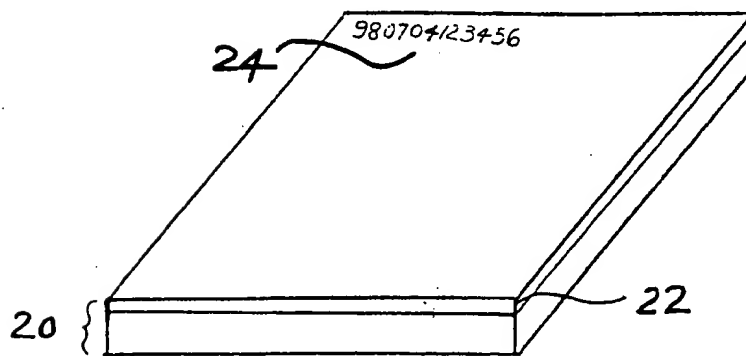


FIGURE 2

30

980704123456	~31
methylphenidate - 20mg	~32
ABC Manufacturing Co.	~33
980720	~34
XYZ Distribution Inc.	~35
980727	~36
Joe Pharmacist	~37
980803	~38
Jane D. Patient	~39

FIGURE 3

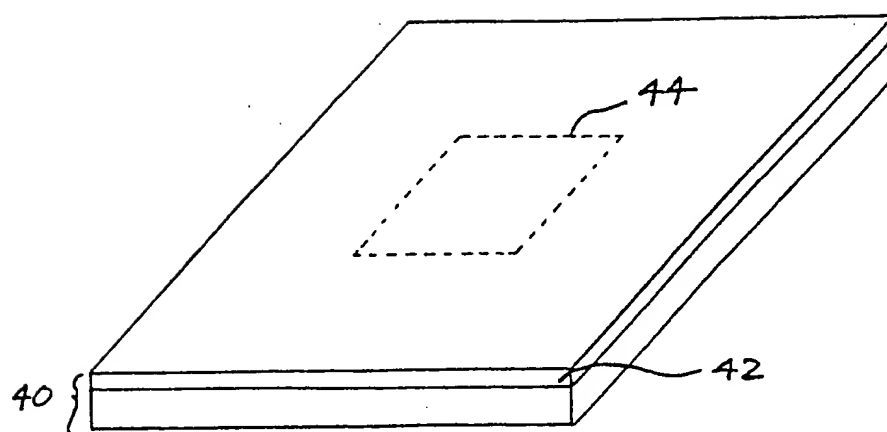


FIGURE 4

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/16042

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G06F19/00 G06K19/00 G06F17/60

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G06F G06K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 28676 A (PYXIS CORP) 2 July 1998 (1998-07-02)	1,2,4-12
Y	page 1, line 10 -page 6, line 15 page 20, line 1 - line 15 ---	3
Y	US 5 448 110 A (TUTTLE ET AL) 5 September 1995 (1995-09-05) column 1, line 16 -column 3, line 14 column 6, line 12 -column 7, line 47; figure 1 ---	3
X	WO 97 07473 A (PATIENT SOLUTIONS INC) 27 February 1997 (1997-02-27) page 5, line 23 -page 11, line 12; figures 1-5 --- -/--	1,2,4, 8-10



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/16042

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